UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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| CINDY BURTON,<br><br>Plaintiff,<br><br>VS.<br><br>WYETH-AYERST LABORATORIES DIVISION OF AMERICAN HOME PRODUCTS CORPORATION, ET AL.,<br><br>Defendants. | ) | CIVIL ACTION NO.<br><br>3:99-CV-0305-G<br><br>**ECF** |

**MEMORANDUM OPINION AND ORDER**

Before the court are the motions by the defendant Wyeth-Ayerst Laboratories ("Wyeth" or "the defendant") to exclude the plaintiff's expert testimony regarding pulmonary hypertension medical prognosis, to exclude evidence that the plaintiff's condition will progress or that the plaintiff will need heart valve surgery in the future, to exclude expert testimony of causation, and for partial summary judgment. For the reasons stated herein, the motions to exclude evidence regarding the pulmonary hypertension medical prognosis and for partial summary judgment are granted in part

and denied in part. The motions to exclude causation testimony and to exclude the expert testimony regarding the plaintiff's alleged heart valve injury are denied.

## I. BACKGROUND

This case stems from the ingestion by the plaintiff Cindy Burton ("Burton" or "the plaintiff") of certain diet drugs manufactured by Wyeth. Between 1996 and 1997, Burton was prescribed and used two products manufactured by Wyeth -- Pondimin and Redux -- to combat obesity. These products contained the drugs fenfluramine and dexfenfluramine, which are in the broad category of drugs known as anorexigens. Burton claims that as a result of such use, she now suffers from two ailments: heart valve regurgitation and pulmonary arterial hypertension. Originally filed in state court, the case was removed to this court in February 1999; in October 1999, the Judicial Panel on Multidistrict Litigation ordered the case transferred to the United States District Court for the Eastern District of Pennsylvania for coordinated and consolidated pretrial proceedings. The case remained before the transferee court until August 2, 2006, when it was conditionally remanded to this court. Following a status conference and the entry of a scheduling order, the instant motions, among others,[1] were filed.

[1] By separate order the court has resolved the defendant's motion to limit the testimony of the plaintiff's generic experts and the defendant's motion to exclude the expert testimony of Michael P. Elkin.

## II. ANALYSIS

Both Wyeth's motion to exclude expert testimony regarding Burton's pulmonary hypertension prognosis and its motion to exclude expert testimony regarding the progression of her heart valve regurgitation arise under FED. R. EVID. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The defendant's motion to exclude expert testimony on the issue of causation and the defendant's motion for partial summary judgment arise under a challenge to the sufficiency of the evidence as required under Texas state law.

### A. Evidentiary Challenges Under *Daubert*

FED. R. EVID. 702 provides that a duly qualified individual may provide opinion testimony as to "scientific, technical, or other specialized knowledge" if such information "will assist the trier of fact to understand the evidence or to determine a fact in issue." According to the rule, the expert testimony is limited to testimony that is both based upon sufficient facts or data and is the product of reliable principles and methods. FED. R. EVID. 702. Furthermore, the expert witness must have applied the principles and methods reliably to the facts of the case. *Id.* These prerequisites to the admissibility of expert testimony have been applied as a two-part test: reliability and "fit." See *Daubert*, 509 U.S. at 590-91; FED. R. EVID. 702 advisory committee's note.

Following the Supreme Court's decision in *Daubert*, it is the duty of the trial court to serve a gatekeeping function, excluding from the jury unreliable or irrelevant

expert testimony. *Daubert*, 509 U.S. at 589. Courts are to apply this gatekeeping function to all expert testimony, not just science-based expert testimony. *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999); *Black v. Food Lion, Inc.*, 171 F.3d 308, 310 (5th Cir. 1999). To aid in the exercise of this gatekeeping function, the Supreme Court set forth a non-exhaustive list of factors for trial courts to consider: (1) "whether [the theory or technique] can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) "the known or potential rate of error"; (4) "the existence and maintenance of standards controlling the [theory or] technique's operation"; and (5) whether the theory or technique has "general acceptance" within the scientific community. *Daubert*, 509 U.S. at 593-94; see also *Vargas v. Lee*, 317 F.3d 498, 500 (5th Cir. 2003).

Application of the *Daubert* factors and any other relevant factors used to determine the admissibility of expert testimony is left to the judgment of the trial court and reviewed only under an abuse of discretion standard. *Vargas*, 317 F.3d at 500-01. When determining the admissibility of the expert testimony, the trial court is not to consider the conclusions generated by the expert witness, but only the principles and methodology used to reach those conclusions. *Daubert*, 509 U.S. at 595. When the principles and methodology are sufficient to allow the expert opinion to be presented to the jury, the party challenging the testimony must resort to

"[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" as the means to attack "shaky but admissible evidence." *Id.* at 596.

1. *Motion to Exclude Testimony Regarding Pulmonary Arterial Hypertension Medical Prognosis*

Before embarking on an analysis of the specific challenge being raised, the court first must set forth background information regarding the disease of pulmonary hypertension. Pulmonary arterial hypertension ("PAH"), at its most elementary level, is a physical finding of elevated blood pressure in the lungs. *See* Wyeth's Brief in Support of Its Motion to Exclude Plaintiff's Expert Testimony Regarding Pulmonary Hypertension Medical Prognosis ("Motion to Exclude PAH Testimony") at 1; Brief in Support of Plaintiff's Response to Defendant Wyeth's Motion for Partial Summary Judgment ("Response to Motion for Summary Judgment") at 3. The manner through which PAH is diagnosed is the use of a right heart catheterization whereby a physician can measure the blood pressure. *See* Motion to Exclude PAH Testimony at 1; Response to Motion for Summary Judgment at 3. If the subject's arterial pressure exceeds certain standards (to be discussed *infra*), then the subject can be diagnosed as having PAH. *See* Motion to Exclude PAH Testimony at 1; Response to Motion for Summary Judgment at 3.

The crux of Wyeth's motion to exclude the experts' testimony regarding Burton's pulmonary hypertension prognosis stems from the standards used to

diagnose PAH. It appears to be a generally accepted proposition that a patient has PAH when the blood pressure in the pulmonary artery is greater than 25 mmHg when at rest or greater than 30 mmHg during exercise. *See* Motion to Exclude PAH Testimony at 1-2. It is undisputed that the right heart catheterizations performed on Burton have never shown a pressure of greater than 25 mmHg while at rest; the diagnosis by her physicians that she has PAH is based on the fact that the right heart catheterizations have demonstrated pressure greater than 30 mmHg with exercise. *See* Motion to Exclude PAH Testimony at 2; Plaintiff's Brief in Support of Its Response to Defendant Wyeth's Motion to Exclude Plaintiff's Expert Testimony Regarding Pulmonary Hypertension Medical Prognosis ("Response to Motion to Exclude PAH Testimony") at 3.

Wyeth argues that PAH is an umbrella term encompassing two different diseases: "exercise-induced PAH" and "resting PAH." *See* Motion to Exclude PAH Testimony at 2-3. According to Wyeth, although resting PAH is accompanied by the possibility of debilitating -- if not fatal -- outcomes, the prognosis for persons afflicted with exercise-induced PAH is unknown. See *id.* at 2. Furthermore, Wyeth avers that there is no scientific evidence that having exercise-induced PAH will eventually progress to resting PAH. See *id.* at 2-3. Thus, Wyeth asks the court to exclude any expert testimony regarding injuries stemming from resting PAH and any expert

testimony indicating a prognosis that Burton's exercise-induced PAH will progress to resting PAH in the future.

Burton, on the other hand, argues that there is but one disease -- PAH -- and that any distinction between resting PAH and exercise-induced PAH is artificial, done by Wyeth only for litigation purposes. *See* Response to Motion for Summary Judgment at 9. According to Burton, diagnosing PAH involves an "either/or" criterion: pressure *either* greater than 25 mmHg while at rest *or* greater than 30 mmHg while exercising. See *id.* Burton concedes that she will not present evidence indicating that her condition will worsen, but she does wish to offer evidence about the full range of PAH injuries so that she can recover future medical expenses. *See* Response to Motion to Exclude PAH Testimony at 2, 4.

The question of whether resting PAH and exercise-induced PAH are different diseases presents a question of first impression for the court. If Wyeth is correct -- that is, if exercise-induced PAH and resting PAH are different diseases -- then the proposed expert testimony regarding future medical damages stemming from resting PAH should be excluded. Under Texas law, to recover damages for diseases that may develop in the future, the plaintiff must establish by a preponderance of the evidence that the as yet undiagnosed disease will develop in the future. See *Pustejovsky v. Rapid-American Corporation*, 35 S.W.3d 643, 652 (Tex. 2000) ("It is our long-established rule that a plaintiff may recover damages for a *disease* that may

develop in future years only if the person establishes that there is a reasonable medical probability that the disease will appear. Courts have interpreted this test to mean that the plaintiff must demonstrate a greater than fifty percent chance of incurring the future damages") (internal citations omitted) (emphasis added). The unique quandary presented to the court is how to make the determination that exercise-induced PAH is a different disease than resting PAH.

In support of its argument, Wyeth points to various statements made by the proposed expert witnesses in this case when describing Burton's condition. Dr. Steven Koenig, M.D., the defendant's expert, states that Burton "has no resting pulmonary hypertension." Amended Report of Steven Koenig, M.D. ("Koenig Report") ¶ 31, *attached to* Appendix of Exhibits to Wyeth's Brief in Support of Its Motion to Exclude Plaintiff's Expert Testimony Regarding Pulmonary Hypertension Medical Prognosis ("Appendix to Motion to Exclude PAH Testimony") *as* Exhibit 1. However, the description of Burton's condition as being "exercise-induced" is not limited to Wyeth's experts; the plaintiff's own expert witnesses echo the same description. *See* Report of Harold I. Palevsky, M.D. at 17 ("All of these findings are diagnostic of exercised-induced pulmonary arterial hypertension . . ."), *attached to* Appendix to Motion to Exclude PAH Testimony *as* Exhibit 2; Deposition of Michael Poon, M.D. at 45, Mar. 29, 2005 ("She was found to have mild exercise-induced pulmonary hypertension . . ."), *attached to* Appendix to Motion to Exclude PAH

Testimony *as* Exhibit 4; Deposition of Richard Channick, M.D. at 53-54, Apr. 5, 2005 ("[S]he did not have resting pulmonary hypertension"), *attached to* Appendix to Motion to Exclude PAH Testimony *as* Exhibit 5; Deposition of Waenard Miller, M.D. at 78, Aug. 30, 2002 ("Q. And I think Dr. Poon concluded that there was exercise-induced pulmonary hypertension, correct? A. Exactly"), *attached to* Appendix to Motion to Exclude PAH Testimony *as* Exhibit 7. While the statements by these various experts lend some credence to Wyeth's argument that these are actually two different diseases, the inquiry must not end there. Of greater importance in the court's estimation is the manner in which these same experts define PAH.

Not one of the experts, including Wyeth's own expert, posits a definition of PAH that coincides with Wyeth's argument that PAH is an umbrella term encompassing two separate diseases. All of the experts who provided a definition of PAH are in agreement as to what constitutes the disease. "[T]he accepted hemodynamic criteria . . . that define PAH are: (1) a mean pulmonary artery pressure (PAP) > 25mmHg at rest *or* > 30 mmHg with exercise; (2) a pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHG; and (3) an increased pulmonary vascular resistance (PVR) > 3 Wood units." Koenig Report ¶ 11 (emphasis added); *see also* Report of Harold I. Palevsky, M.D. at 13 ("Pulmonary Arterial Hypertension (PAH) is clinically defined as a mean pulmonary arterial pressure (PAP) more than 25 mmHg at rest *or* more than 30 mmHg during exercise . . ."") (emphasis added); Report

of Hunter Clay Champion, M.D. at 635 ("The accepted hemodynamic criteria for PAH . . . are: (1) a mean pulmonary artery pressure > 25 mmHg at rest *or* > 30 mmHg with exercise . . ."), *attached to* Appendix of Exhibits for Plaintiff's Responses to Wyeth's January 2, 2007 Motions ("Appendix to Responses") *as* Exhibit 10.

The issue presented by Wyeth seeks to have the court carve out a distinction between these two diseases essentially as a matter of law. Based on the evidence before the court, such a distinction cannot be drawn. Medical science appears not to have made this distinction, and neither will this court. Accordingly, to the extent the motion seeks to exclude all of the expert testimony regarding the injuries associated with what Wyeth describes as resting PAH, the motion is denied.

To the extent that Wyeth seeks to limit the testimony of Burton's experts with regard to their testimony about a poor prognosis for Burton, the motion to exclude such testimony is granted. Wyeth argues that there is insufficient medical proof to conclude that a person who exhibits PAH only through exercise will eventually progress to having PAH which exhibits itself while at rest. On this point, the plaintiff concedes; Burton represents that she will not proffer expert testimony "with

reasonable certainty, that Ms. Burton's P[A]H will worsen in the future."[2] Response to Motion to Exclude PAH Testimony at 1.

The question of what damages evidence Burton can introduce remains. Texas has adopted the reasonable probability rule for recovery of future medical expenses. See *Bituminous Casualty Corporation v. Cleveland*, __ S.W.3d __, 2006 WL 1418624, at *3 (Tex. App.--Amarillo 2006, no pet.). Under Texas law, the plaintiff must demonstrate that there is a reasonable probability that future medical expenses resulting from the injury will be incurred. See *Doctor v. Pardue*, 186 S.W.3d 4, 20 (Tex. App.--Houston [1st Dist.] 2006, pet. denied). Reasonable probability requires that the plaintiff prove there is a more than 50 percent chance such expenses will be incurred. See *Pilgrim's Pride Corporation v. Smoak*, 134 S.W.3d 880, 905 (Tex. App.--Texarkana 2004, pet. denied). While expert testimony is preferred, it is not required. See *Antonov v. Walters*, 168 S.W.3d 901, 908 (Tex. App.--Fort Worth 2005, pet. denied). "The jury may make its award based upon the nature of the injuries, the medical care rendered before trial, and the condition of the injured party

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[2] The court notes that despite the plaintiff's concession, Dr. Harold Palevsky ("Palevsky"), in his most recent declaration, states, "The progression from 'normal' to exercise-associated pulmonary hypertension and then to resting pulmonary hypertension and the development of right heart failure is the progression that every patient with pulmonary hypertension goes through. This has been recognized for decades . . ."). Declaration of Harold Palevsky, M.D. on Cynthia Burton ("Palevsky Declaration") at 351, *attached to* Appendix to Responses *as* Exhibit 7. Such statements are inadmissible at trial in light of both the concession made by the plaintiff and the fact that this assertion appears to be unsupported.

at the time of trial." *City of San Antonio v. Vela*, 762 S.W.2d 314, 321 (Tex. App.--San Antonio 1988, writ denied).

Accordingly, Burton can present evidence regarding her future medical expenses.[3] While this evidence may produce statements regarding the possibility of progression of the alleged exercise induced PAH, thorough cross examination and comprehensive jury instructions will be sufficient to alleviate any confusion for the jury that may result from the inclusion of such evidence.

In its final argument regarding the PAH expert testimony, Wyeth avers that Burton should not allowed to recover for her mental anguish associated with the possibility that her PAH may progress or that she may suffer from the outcomes associated with resting PAH. *See* Motion to Exclude PAH Testimony at 17 n.5 (quoting *Exxon Corporation v. Makofski*, 116 S.W.3d 176, 190 (Tex. App.--Houston [14th Dist.] 2003, pet. denied) (stating Texas law "prohibits recovery of mental anguish damages for an increased risk of developing a *disease* that is not presently manifest") (emphasis added). Again, this argument is based on the assumption that

[3] It does not appear that Wyeth contests Burton's right to present evidence of future medical damages for the level of medical care that she currently requires. Beyond that, it is unclear to the court what evidence, if any, Burton intends to introduce to meet her burden of proving the reasonable probability of future medical expenses. That is, in light of her concession that she will not introduce evidence that her disease will progress and the court's observation that Palevsky's testimony of progression PAH is unreliable, the court is unaware of what evidence Burton will attempt to introduce to prove future medical damages beyond the level of care she currently receives. Challenges to such evidence can be addressed as the need arises.

exercise-induced PAH and resting PAH are different diseases. Because the court finds that the medical terminology supports the conclusion that there is only one disease, PAH, Burton is permitted to offer evidence regarding her mental anguish as it relates to her alleged injuries.

Thus, Wyeth's motion to exclude expert testimony indicating that Burton's disease will progress is granted. In all other respects, the motion is denied.

2. *Motion to Exclude Evidence Regarding Progression of Plaintiff's Alleged Heart Valve Regurgitation*

Wyeth seeks to exclude the testimony of Dr. Waenard L. Miller ("Miller") regarding his opinion that Burton's alleged heart valve regurgitation is progressive in nature. The defendant asks the court to exclude this testimony under *Daubert*, arguing that Miller's opinion is unsupported by, and in contradiction to, the scientific literature because the studies upon which Miller relies were not specific to heart valve regurgitation stemming from the use of diet drugs. *See* Defendant Wyeth's Brief in Support of Its Motion to Exclude Unreliable Evidence that Plaintiff's Condition Will Progress and/or that Plaintiff Will Need Heart Valve Surgery in the Future ("Motion to Exclude Heart Valve Testimony") at 3-4. As stated above, the Supreme Court in *Daubert* provided a non-exhaustive list of factors for trial courts to consider when exercising their gatekeeping function over expert testimony. *Daubert*, 509 U.S. at 593-94. Included in this list were: (1) "whether [the theory or technique] can be

(and has been) tested" and (2) "whether the theory or technique has been subjected to peer review and publication." *Id.* It is upon these two factors that Wyeth focuses.

In response, Burton avers that Miller's opinion regarding progression of her heart valve regurgitation and need for heart valve surgery in the future is reliable and based on sufficient evidence. Specifically, Burton asserts that Miller's expert testimony is based on proper scientific studies, even though the studies did not look directly at diet-drug related heart valve regurgitation. *See* Plaintiff's Brief in Support of Response to Defendant Wyeth's Brief in Support of Its Motion to Exclude Unreliable Evidence that Plaintiff's Condition Will Progress or that Plaintiff Will Need Heart Valve Surgery in the Future ("Response to Motion to Exclude Heart Valve Testimony") at 6. Additionally, Burton attacks the studies cited by Wyeth that it claims to be in contradiction to Miller's testimony. See *id.* at 7-10.

Miller opines that Burton's valvular heart disease will progress to the point of needing surgery, and he bases this opinion on various studies that indicate valvular heart disease to be a progressive disorder. Declaration of Waenard L. Miller, M.D. Regarding Cynthia Burton ("Miller Declaration") at 772, *attached to* Appendix to Responses *as* Exhibit 17. Miller states that valvular heart disease causes damage to the valve structure over an extended period of time due to the improper closing of the valve, which will occur thousands of times per day. *Id.* In a deposition taken in 2002, Miller stated that he believes this constant regurgitation will lead to damage

requiring surgery within ten to fifteen years.[4] Deposition of Waenard Miller, M.D. at 23, Aug. 30, 2002 , *attached to* Appendix of Exhibits to Defendant Wyeth's Brief in Support of Its Motion to Exclude Unreliable Evidence that Plaintiff's Condition Will Progress and/or that Plaintiff Will Need Heart Valve Surgery in the Future ("Appendix to Motion to Exclude Heart Valve Testimony") *as* Exhibit 12. He stated that he bases this opinion on both peer reviewed epidemiological studies and "accepted hemodynamic principles." *See* Miller Declaration at 772. In his expert report, Miller cites several studies upon which he relies in reaching his conclusion. See *id.* Miller further asserts that the etiology of the acquired heart valve disease is irrelevant with regards to the issue of whether the disease will progress. *Id.*

At no point does Wyeth challenge the validity of the studies and hemodynamic principles relied on by Miller. Instead, Wyeth attempts to attack Miller's *conclusion*, not methodology, by offering competing studies. For example, Wyeth asserts, through its expert Mitchell Levine M.D., that the etiology of the acquired valvular heart disease is relevant and that certain scientific studies indicate that subjects who acquired valvular heart disease following diet drug exposure are more likely to remain stable or regress than to progress. Affidavit of Mitchell Levine, M.D., BSC, MSC,

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[4] Given the date of the deposition, Miller's testimony equates to a conclusion that Burton will need heart valve surgery sometime between 2012 and 2017, which would be fifteen to twenty years following Burton's cessation of the diet drug use.

FRCPC, FISPE at 41, *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 15.

The court concludes that there is sufficient support for Miller's opinion to render it reliable under *Daubert*. While Wyeth presents the court with some studies and abstracts that provide an arguable basis to question Miller's opinion, these studies and abstracts do not make Miller's opinion inadmissible. In support of its argument that the progression of diet drug related valvular heart diseases differs from the progression of other valvular heart disease, Wyeth directs the court's attention to eight documents.[5] Two of the documents relied on are abstracts and provide the court with insufficient data to determine the weight of the conclusions reached therein.[6]

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[5] Of the eight documents, the court will not give in depth treatment to two of the documents. The conclusions drawn in one of the studies is not directly relevant to the issue at hand and provides only circumstantial support for Wyeth's argument. *See* Hershel Jick, *et al.*, *A Population-Based Study of Appetite-Suppressant Drugs and the Risk of Cardiac Valve Regurgitation*, 339 NEW. ENG. J. MED. 719 (1998) (concluding that exposure to fenfluramine or dexfenfluramine for four months or longer is associated with an increased risk of cardiac-valve disorders but noting that none of the observed subjects required heart valve surgery), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 16. The other study focuses on a population too few in number to warrant significance. *See* Donald D. Hensrud, *et al.*, *Echocardiographic Improvement Over Time After Cessation of Use of Fenfluramine and Phentermine*, 74 MAYO CLINIC PROC. 1191, December 1999 (drawing its conclusions based on a follow-up echocardiogram six months after discontinuation of diet drug use on a population of only 15 patients), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 18.

[6] *See* Mehmood A. Khan, *et al.*, *Does the Severity of Appetite*

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The more detailed studies upon which Wyeth relies suffer from a separate problem -- potential bias. Four of the studies relied on by the defendant were funded by Wyeth and at least one of those studies was edited by Wyeth.[7] *See* Wyeth's

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[6](...continued)
*Suppressant-Related Aortic Valve Insufficiency Change over Time after Stopping Exposure to Drug?*, 102 CIRCULATION 1803 (2000) (concluding after an examination over an eleven month period that patients with aortic insufficiency caused by diet drugs were more likely to improve than progress), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 17; James P. Eichelberger, *et al.*, *15 Year Outcome Data on Patients Treated With Fenfluramine/Phentermine Combination*, 12 J. AM. SOC'Y ECHOCARDIOGRAPHY (1999) (concluding after an evaluation of 80 patients exposed to diet drugs 15 years after cessation of use of the drugs that the evaluation "suggests a lack of significant regression or progression . . ."), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 19.

[7] Steven T. Mast, *et al.*, *The Progression of Fenfluramine-Associated Valvular Heart Disease Assessed by Echocardiography*, 134 ANNALS INTERNAL MED. 261 (2001), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 20; Neil J. Weissman, *et al.*, *Natural History of Valvular Regurgitation 1 Year after Discontinuation of Dexfenfluramine Therapy*, 134 ANNALS INTERNAL MED. 267 (2001), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 21; Julius M. Gardin, *et al.*, *Clinical and Echocardiographic Follow-up of Patients Previously Treated with Dexfenfluramine or Phentermine/Fenfluramine*, 286 JAMA 2011 (2001), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 22; Ravin Davidoff, *et al.*, *Echocardiographic Examination of Women Previously Treated with Fenfluramine*, 161 ARCHIVES INTERNAL MED. 1429 (2001), *attached to* Appendix to Motion to Exclude Heart Valve Testimony *as* Exhibit 23. Furthermore, there is at least some evidence that Wyeth considers the cost of these studies to be part of the litigation costs associated with these diet drug cases. *See* Letter to J.R. Stafford & R.G. Blount from J.R. Considine & T.L. Conklin (Feb. 25, 1998) (suggesting that the cost of these studies could be submitted as "damages" to Wyeth's insurer because such work is reasonably necessary to defend [Wyeth] against the bodily injury claims being alleged"), *attached to* Appendix to Responses *as* Exhibit 20. The fact that these studies may have been funded for the purpose of litigation does not render them inadmissible (especially since the studies were published and subject to peer review); however, that fact -- coupled with the financial backing and editorial control

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Response to Plaintiff Sandra Bounds' Deposition Upon Written Questions at 4-5, 6 (listing the studies funded by Wyeth and responding "Yes" to the question "Did AHP/Wyeth make suggested changes (a/k/a editorial suggestions) to one or more of the studies you just listed before they were published?"), *attached to* Appendix to Responses *as* Exhibit 18. Additionally, three of the studies observed the patients over a relatively short period of time. *See* Mast, *supra*, at 62 (stating that the mean time between the first and last echocardiograms to be 356 ± 224 days); Weissman, *supra*, at 68 (indicating that the "follow-up" echocardiogram was taken 11.4 ± 1.0 months following discontinuation of diet drug use); Gardin, *supra*, at 74 (stating that the follow-up echocardiogram was 12 to 13 months following discontinuation of the drug therapy).

The one study submitted by Wyeth that was conducted over a somewhat substantial period of time (4.4 years following cessation of diet drug use) reaches conclusions unrelated to the instant case. *See* Davidoff, *supra* at 83-84. Unlike Burton, the population observed in that study was limited to persons with three months or less of exposure to fenfluramine-based anorexigens. *Id.* Furthermore, as understood by the court, the study merely reaches a conclusion regarding the absence of a latency period associated with exposure to these diet drugs. *Id.*

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[7](...continued)
exhibited by Wyeth -- leads the court to treat such evidence with at least a modicum of skepticism.

At best, these studies demonstrate that Miller's opinion may be one of those "shaky but admissible" opinions referred to in *Daubert*, for which cross-examination and proper jury instructions are the appropriate remedy, and these studies cited by Wyeth provide the defendant with fertile ground for such examination. However, these studies are insufficient to undermine the reliability of Miller's opinion to the point of rendering it inadmissible. Accordingly, the motion to exclude testimony that Burton's heart valve condition will progress or that she will need heart valve surgery in the future is denied.

B. Motion for Partial Summary Judgment

Wyeth moves for summary judgment on Burton's claim that Wyeth's products caused her to develop PAH.[8] This motion incorporates Wyeth's motion to exclude causation testimony.[9] Specifically, Wyeth argues summary judgment should be

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[8] In its motion, Wyeth also moved for summary judgment on Burton's claims of conspiracy and negligence *per se*. Wyeth's Brief in Support of Motion for Partial Summary Judgment at 32, 35. Burton, in her response to the motion for summary judgment, stated that she "withdraws and abandons those claims." Response to Motion for Summary Judgment at 2. Accordingly, Wyeth's motion for summary judgment on these two claims is granted.

[9] Wyeth, by separate motion, moved this court to exclude, under FED. R. EVID. 702, 403, and *Daubert*, all expert testimony "that diet drugs caused her to develop Exercise Induced Pulmonary Arterial Hypertension." Wyeth's Brief in Support of Motion to Exclude Expert Testimony of Causation at 1. However, the motion itself contains no argument or authorities but incorporates by reference Wyeth's motion for partial summary judgment. The court will address the challenge to the causation testimony within the analysis of the motion for partial summary judgment since the arguments of both parties regarding the causation evidence are

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entered in its favor because under Texas law there is insufficient evidence to demonstrate causation between its products and exercise-induced PAH.

To establish a causal link between her ingestion of the defendant's product and her alleged PAH, Burton relies on expert testimony. Specifically, she relies on the testimony of Palevsky.[10] According to Palevsky, various studies have established a causal connection between the use of Wyeth's diet drugs and PAH. *See* Declaration of Harold Palevsky, M.D. on Cynthia Burton ("Palevsky Declaration") at 352, *attached to* Appendix to Responses *as* Exhibit 7. Palevsky cites mainly the International Primary Pulmonary Hypertension Study ("IPPHS"); in a footnote, he

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[9](...continued)
contained in the briefs on the motion for partial summary judgment.

[10] Burton provides testimony from other experts besides Palevsky. However, upon review of the reports and testimony provided by these additional experts, the court finds Palevsky's statements to be comprehensive. In no instance does he fail to mention any studies upon which the other experts rely. *See*, *e.g.*, Deposition of Richard Channick, M.D. at 679, Nov. 1, 2006 (answering "That's correct" to the question "would you agree with me that there are -- there's ample epidemiological evidence to demonstrate that there is an increased risk of contracting pulmonary hypertension associated with the use of fenfluramines?" without naming any specific epidemiological studies to support that answer), *attached to* Appendix to Responses *as* Exhibit 13.

refers to additional studies,[11] including the Surveillance of North American Pulmonary Hypertension ("SNAPH"). *Id.*

1. *Legal Standard for Summary Judgment*

Summary judgment is proper when the pleadings and evidence before the court show that no genuine issue exists as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); see also *Celotex Corporation v. Catrett*, 477 U.S. 317, 323 (1986). The disposition of a case through summary judgment "reinforces the purpose of the Rules, to achieve the just, speedy, and inexpensive determination of actions, and, when appropriate, affords a merciful end to litigation that would otherwise be lengthy and expensive." *Fontenot v. Upjohn Company*, 780 F.2d 1190, 1197 (5th Cir.1986).

While all of the evidence must be viewed in a light most favorable to the nonmovant, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (citing *Adickes v. S.H. Kress & Company*, 398 U.S. 144, 158-59 (1970)), neither conclusory allegations nor unsubstantiated assertions will satisfy the nonmovant's summary judgment burden. *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir.2002) (citing

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[11] The additional studies cited by Palevsky are: Simmonneau, *et al.*, *Primary Pulmonary Hypertension Associated with the Use of Fenfluramine Derivatives*; Mark, *et al.*, *Fatal Pulmonary Hypertension Associated with Short Term Use of Fenfluramine and Phentermine*; Walker, A.M., *et al.*, *Temporal Trends and Drug Exposures in Pulmonary Hypertension: An American Experience*. The plaintiff neither provided the court with copies of these articles nor discussed the validity of these studies under the requirements of *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997) (discussed *infra*).

*Little v. Liquid Air Corporation*, 37 F.3d 1069, 1075 (5th Cir.1994) (en banc)). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248.

The movant makes the necessary showing by informing the court of the basis of its motion and by identifying the portions of the record which reveal there are no genuine material fact issues. *Celotex*, 477 U.S. at 323. The pleadings, depositions, admissions, and affidavits, if any, must demonstrate that no genuine issue of material fact exists. FED. R. CIV. P. 56(c).

If the movant makes the required showing, the nonmovant must then direct the court's attention to evidence in the record sufficient to establish that there is a genuine issue of material fact for trial. *Celotex*, 477 U.S. at 323-24. To carry this burden, the "opponent must do more than simply show . . . some metaphysical doubt as to the material facts." *Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corporation*, 475 U.S. 574, 586 (1986). Instead, the nonmovant must show that the evidence is sufficient to support a resolution of the factual issue in her favor. *Anderson*, 477 U.S. at 249. When conflicting evidence is presented, the court is not permitted to make credibility determinations regarding the evidence. See *Lindsey v. Prive Corporation*, 987 F.2d 324, 327 (5th Cir.1993). The nonmovant cannot survive a motion for summary judgment, however, by merely resting on the allegations in her pleadings. *Isquith for and on behalf of Isquith v. Middle South Utilities, Inc.*, 847 F.2d

186, 199 (5th Cir.), *cert. denied*, 488 U.S. 926 (1988); see also *Celotex*, 477 U.S. at 324.

### 2. *The Use of Epidemiological Studies to Establish Causation in Toxic Tort Cases*

The Texas Supreme Court in *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997), set forth specific guidelines for the use of epidemiological studies to prove causation in tort claims.[12] The *Havner* court began by noting the difficulty of establishing causation in toxic tort cases. "In some cases, controlled scientific experiments can be carried out to determine if a substance is capable of causing a particular injury or condition . . . However, in many toxic tort cases, direct experimentation cannot be done, and there will be no reliable evidence of specific causation." *Id.* at 714-15. When such direct evidence is unavailable, claimants may attempt to demonstrate an increased risk posed by exposure to the substance in question in an effort to establish causation; this is generally done through epidemiological studies. *Id.* at 715. "Epidemiological studies examine existing

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[12] Though not directly challenged by the plaintiff in this case, the court notes that there is at least some controversy over whether *Havner*'s requirements are applicable in federal cases where subject matter jurisdiction is based on diversity of citizenship. This court agrees with the conclusion reached by other federal courts that have addressed the issue: *Havner's* standards are substantive, not procedural, requirements. See *Cano v. Everest Minerals Corporation*, 362 F. Supp. 2d 814, 821-22 (W.D. Tex. 2005) ("If evidence is admissible under federal procedural law but fails to constitute 'some evidence' under Texas substantive law, the Plaintiffs' victory on the admissibility question would be a hollow one, as the evidence would be deemed insufficient as a matter of law to survive summary judgment").

populations to attempt to determine if there is an association between a disease or condition and a factor suspected of causing that disease or condition." *Id.* The court cautioned, however, that even if an epidemiological study demonstrates an increased risk among those exposed to the substance in question, the increased risk is not a showing of actual causation. *Id.* Proceeding on a causation theory rooted in epidemiological studies "concedes that science cannot tell us what caused a particular plaintiff's injury." *Id.* at 714. *Havmer* held that when attempting to prove causation through epidemiological studies, failure to meet the requirements set forth in the opinion would render the studies unreliable. *Id.* at 717. Thus, the studies and any expert testimony based thereon would not constitute "some evidence" upon which the finder of fact could determine causation. *Id.* at 714. The requirements of *Havner* can be divided into two categories: requirements to prove general causation and requirements to prove specific causation.[13]

Because epidemiological studies do not actually demonstrate causation, *Havner* set forth relatively specific requirements for the use of epidemiological studies when attempting to prove general causation. The court held, that at a minimum, for an

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[13] To prevail in a toxic tort case, the plaintiff must demonstrate both general causation and specific causation. See *Mobil Oil Corporation v. Bailey*, 187 S.W.3d 265, 270 (Tex. App.--Beaumont 2006, pet. denied). That is, the plaintiff must prove that the substance is capable of causing the specific injury of which she complains, and secondly, the plaintiff must prove that her injury was caused by the substance in question. See *id.* To establish causation, the plaintiff must prove that it is more likely than not that the defendant's product caused her injuries. *Havner*, 953 S.W.2d at 715.

epidemiological study to constitute evidence of causation: (1) the study must demonstrate "more than doubling of the risk" due to exposure (*i.e.*, a relative risk of greater than 2.0), *id.* at 717-18; (2) the study must have a confidence interval that does not include 1.0, *id.* at 723; and (3) the study must have a confidence (or significance) level of at least 95 percent, *id.* at 724. See also *Matt Dietz Company v. Torres*, 198 S.W.3d 798, 801-02 (Tex. App.--San Antonio 2006, pet. denied). Furthermore, the court held "[i]solated case reports" and "random experience" to be insufficient and that an expert "cannot dissect a study, picking and choosing data, or 'reanalyze' the data to derive a higher relative risk." *Havner*, 953 S.W.2d at 720. Additionally, the submission of a single epidemiological study without more is insufficient to establish causation. See *id.* at 718 ("We do not hold . . . that a single epidemiological test is legally sufficient evidence of causation"); see also *Mobil Oil Corporation*, 187 S.W.3d at 274; *Daniels v. Lyondell-Citgo Refining Company, Ltd.*, 99 S.W.3d 722, 727 (Tex. App.--Houston [1st Dist.] 2003, no pet.); *Coastal Tankships, U.S.A., Inc. v. Anderson*, 87 S.W.3d 591, 616-17 (Tex. App.--Houston [1st Dist.] 2002, pet. denied); *Austin v. Kerr-McGee Refining Corp.*, 25 S.W.3d 280, 286 (Tex. App.--Texarkana 2000, no pet.). In neither *Havner* nor subsequent cases has the Texas Supreme Court indicated what more than a "single epidemiological test" would constitute legally sufficient evidence.

To show specific causation, the claimant must demonstrate that she is similar to those in the epidemiological study. The *Havner* court stated that such proof would "include" evidence that the claimant "was exposed to the same substance, that the exposure or dose levels were comparable to or greater than those in the studies, that the exposure occurred before the onset of injury, and that the timing of the onset of injury was consistent with that experienced by those in the study." See *Havner*, 953 S.W.2d at 720. Also, to prove specific causation, the claimant must offer evidence negating other plausible causes of the injury or condition. *Id.*

*2. Burton's Claim Regarding PAH*

Wyeth essentially raises a challenge to Burton's ability to prove both general causation and specific causation. The defendant challenges Burton's ability to prove general causation by arguing that she has no epidemiological studies to support her claim that its products allegedly caused her exercise-induced PAH. Wyeth's Brief in Support of Motion for Partial Summary Judgment ("Motion for Summary Judgment") at 25. That is, Wyeth argues that Burton must come forward with epidemiological studies sufficient to meet the requirements of *Havner* that draw a causal connection between Wyeth's products and the specific injury of exercise-induced PAH. See *Havner*, 953 S.W.2d at 725 (noting that an epidemiological study evincing a causal connection between exposure to Bendectin and certain non-limb reduction birth defects could not be used to establish a causal connection between

Bendectin and limb reduction birth defects). This argument, of course, is contingent on the court's acceptance of the assertion by Wyeth that there is a difference between exercise-induced PAH and resting PAH. To the extent that Wyeth's motion relies on the court distinguishing between exercise-induced PAH and resting PAH, the court reiterates its prior conclusion. The experts have provided the court with the definition of only one disease -- PAH. Accordingly, to the extent the motion to exclude causation evidence and the motion for partial summary judgment rely on this distinction, the motion is denied.

Wyeth also challenges the sufficiency of Burton's evidence under the specific causation requirements of *Havner*. In response to Wyeth's motion for summary judgment, Burton points to only two epidemiological studies upon which her expert relies in concluding that her PAH was caused by ingestion of the defendant's products. Response to Motion for Summary Judgment at 7-8. These two studies are the IPPHS study and the SNAPH study. *Id.* at 8. While there is no genuine dispute on this motion that these two studies meet the *Havner* requirements[14] regarding a doubling of the risk, confidence level, and confidence interval, Wyeth challenges Burton's ability to rely on these studies.

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[14] The court notes that Wyeth, in its motion for summary judgment, did not concede that the SNAPH study met the *Havner* requirements, but merely assumed that it did for the purposes of the motion. Defendant Wyeth's Reply Brief in Support of Motion for Partial Summary Judgment at 6. Thus, Wyeth is not precluded from challenging the validity of this study under *Havner* in the future.

*Havner* noted that a plaintiff who is relying on epidemiological studies to establish causation must show that she is similar to those persons studied. 953 S.W.2d at 720. *Havner* listed four factors to demonstrate similarity: (1) exposure to the same substance as those studied; (2) exposure in the same or greater dose than those studied; (3) exposure prior to onset of the injury; and (4) consistency in timing of the injury's onset. 953 S.W.2d at 720. While *Havner* listed only these four factors (plus the requirement that the plaintiff be able to exclude other causes for her injury), the language of the opinion indicated that this list was not exhaustive. See *id.* (stating the plaintiff's showing of similarity would "include" proof of the four factors listed).

Wyeth argues that for a plaintiff to rely on an epidemiological study, the plaintiff must be able to fit herself within the population as defined in the study. *See* Defendant Wyeth's Reply Brief in Support of Motion for Partial Summary Judgment at 4-5. This argument has at least some support under Texas law. See *In re BP Amoco Chemical Company*, No. 14-06-00778-CV, 2007 WL 177437, at *2 (Tex. App.--Houston [14th Dist.] Jan. 25. 2007, no pet.) (stating on an appeal from a trial court order regarding a discovery dispute that "[u]nless a plaintiff can show that he could qualify as a member of the exposed study group, an epidemiological study is irrelevant and misleading to the jury [ citing *Daubert*, 509 U.S. 591-92]. A claimant must show that he or she is similar to those in the studies. *Havner*, 953 S.W.2d at 720. . . .

Because [the plaintiff] has failed to show that he could qualify as a member of those study groups, his request is not reasonably tailored to include only relevant matters"); see also *Stevens v. Secretary of Department of Health & Human Services*, No. 99-594V, 2001 WL 387418, at *13 (Fed. Cl. Mar. 30, 2001) (stating, with regard to a California law with requirements similar to *Havner*, that "a petitioner may successfully demonstrate actual causation by providing a reliable and relevant epidemiological study and establishing that she falls within the parameters of the group associated with the statistically significant relative risk"); *Minnesota Mining and Manufacturing Company v. Atterbury*, 978 S.W.2d 183, 200 (Tex. App.--Texarkana 1998, pet. denied) (stating an expert's failure to account for geographical variations in population as a grounds for determining the testimony to be insufficient to prove causation). According to Wyeth, Burton does not fit within the defined population of either the SNAPH study or the IPPHS study and thus these studies and any expert testimony based thereon cannot constitute "some evidence" of causation.

Wyeth is correct that Burton does not fit within the IPPHS study's population. The IPPHS population was defined more narrowly than the generally accepted definition of PAH. That is, it observed only subjects who had a pulmonary artery pressure of greater than 25 mmHg *while at rest*. *See* IPPHS at 26, *attached to* Appendix to Motion for Summary Judgment *as* Exhibit 2 ("Primary pulmonary hypertension is defined as the presence of a mean pulmonary artery pressure of greater than 25

mmHg at rest"). Assuming without deciding that a plaintiff must prove she could fit within the defined population of an epidemiological study in order for it and expert testimony based thereon to constitute "some evidence" of causation, the court finds that Burton has at least one epidemiological study upon which to rely -- the SNAPH study.

Though Wyeth contends that Burton would not fit within the populations observed in the SNAPH study, upon review of the study it is unclear whether the SNAPH study restricted its population to persons who demonstrate PAH only while at rest. The study reads, "[p]ulmonary hypertension was defined as a mean pulmonary pressure, measured at cardiac catheterization, that was > 25 mmHG . . .". SNAPH at 370, *attached to* Palevsky Declaration, *attached to* Appendix to Responses *as* Exhibit 7. Wyeth makes the logical, though unsupported, argument that because the target measurement of 25 mmHg was used, the study could only have included persons who exhibit PAH while at rest. Despite the logic of this inference, the court cannot find, on the evidence presented, that Burton falls outside the definition of the SNAPH population.

While the SNAPH study standing alone is insufficient to constitute "some evidence" of causation, the SNAPH study, in conjunction with the IPPHS study and the other articles cited by Palevsky are, in this court's judgment, sufficient to

constitute "some evidence."[15] Thus, Palevsky's causation testimony is sufficiently grounded to render it admissible as evidence of causation at trial. Accordingly, there is a genuine dispute on the issue of causation in this case, and summary judgment on Burton's claim of PAH cannot be granted.

## III. CONCLUSION

For the reasons stated herein, the defendant's motion to exclude unreliable evidence that plaintiff's condition will progress or that plaintiff will need heart valve surgery in the future and motion to exclude expert testimony of causation are **DENIED**. The defendant's motion for partial summary judgment and motion to exclude plaintiff's expert testimony regarding pulmonary hypertension medical prognosis are **GRANTED** in part and **DENIED** in part.

**SO ORDERED**.

April 9, 2007.

A. JOE FISH
CHIEF JUDGE

[15] To be clear, the court's finding that Palevsky's testimony is reliable and can constitute "some evidence" is in no way an indication that Palevsky's testimony alone, even when relying on the studies discussed above, will be legally sufficient to meet the "more probable than not" standard Burton must meet to prove causation.